#8
6/2/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Aliberto	)	Art Unit: 3763
Serial No.:	10/057,334	)	Examiner: Thissell
Filed:	January 23, 2002	)	**001/062USA**
For:	CENTRAL VENOUS CATHETER WITH HEAT EXCHANGE MEMBRANE	)	January 10, 2003 750 B STREET, Suite 3120 San Diego, CA 92101

APPEAL BRIEF

Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Sir:

This appeal brief is in response to the second Office Action dated December 31, 2002. This appeal brief is submitted under 35 U.S.C. §134, and is further to Appellant's Notice of Appeal filed herewith.

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(1) Real Party in Interest

The real party in interest is the assignee, Alsius Corp.

(2) Related Appeals/Interferences

No other appeals or interferences exist which relate to the present application or appeal.

(3) Status of Claims

Twice-rejected Claims 5 and 8 are the only claims pending and under consideration. A copy of the claims is in Appendix A.

(4) Status of Amendments

No amendments are outstanding.

(5) Summary of Invention

The invention of Claim 5 is method for treating a human patient by circulating coolant through a heat exchange catheter device (18, Figure 1, page 5) in a patient while preventing infusion of the coolant directly into the patient's bloodstream (page 4, third paragraph) and performing aneurysm surgery (page 10, second full paragraph) while the patient's temperature is below normal body temperature. In contrast, the closed loop heat exchange catheter of Claim 8 is used for a different purpose, namely, using the catheter to maintain a patient temperature pursuant to performing minimally invasive heart surgery on the patient (page 10, third paragraph) while the patient's temperature is below normal body temperature.

(6) Issues

(a) Whether Claim 5 is unpatentable under 35 U.S.C. §103 as being unpatentable over Ginsburg '208 in view of Clifton.

(b) Whether Claim 8 is unpatentable under 35 U.S.C. §103 as being unpatentable over Dato in view of Williamson, IV et al.

(7) Grouping of Claims

The claims are grouped apart since they have been rejected on different grounds.

8(a) Argument

Claim 5 has been rejected under 35 U.S.C. §103 as being unpatentable over Ginsburg, used as a teaching of a cooling catheter but nowhere mentioning aneurysm surgery, in light of Clifton, used as a teaching of correcting an aortic aneurysm during hypothermia but failing to mention the use of heat exchange catheters.

In other words, only the Appellant and the examiner have ever proposed using a cooling catheter during aneurysm surgery. When a patent applicant puts two and two together, it is inventive insight; when done by an examiner after reading the patent application, it is impermissible hindsight.

Where has the rejection gone wrong? First, it takes a teaching of a treatment genus, uncoupled to any particular treatment mode, and transforms it to a teaching of a species coupled to a particularly claimed treatment mode. Specifically, the rejection relies on the simple observation at Ginsburg, col. 2, line 51 to the effect that it "***may be***" desirable to cool a patient during unspecified surgery. Whether the "may be" applies to a particular kind of surgery, much less what kind and under what conditions, is left unsaid. Thus, the relied-upon section of Ginsburg leaves one with little or no expectation of success for applying Ginsburg to any particular kind of surgery, see MPEP §2142 *et seq.*

It must also be pointed out that in the relied-upon section, Ginsburg does not explicitly mention that the cooling for the general purpose of surgery is to be undertaken using a catheter.

Second, the relied-upon teaching of Clifton at col. 1, line 36 mentions only profound hypothermia as a treatment for aneurysm surgery. According to Ginsburg, "profound" hypothermia means using a temperature below 24°C (col. 1, line 34). But Ginsburg contemplates using its catheter to induce much less severe forms of hypothermia, col. 4, lines 15-17 (teaching use of its catheter to lower body temperature only "several degrees" below normal, usually taken to be around 38°C; "several degrees" below that would be in the mild to moderate hypothermic range). So the skilled artisan, in considering Clifton, would be advised that profound hypothermia is required for aneurysm surgery, while Ginsburg advises the artisan that it contemplates using its catheter for inducing much less severe forms of hypothermia. Faced with these conflicting teachings, the skilled artisan would have no motivation to combine Ginsburg with Clifton as proposed.

Appellant notes that Ginsburg mentions using a balloon temperature of zero degrees at col. 8, line 53 but this is nowhere tied to inducing anything beyond moderate hypothermia. Indeed, such a temperature of the relatively small heat exchange element would be expected by the skilled artisan to be necessary (and in fact experience has shown it to be necessary) to maintain core temperature only in the moderate hypothermia range envisioned by Ginsburg, because the body naturally adds heat that overcomes further cooling by the catheter. Thus, the teaching at col. 8 of Ginsburg is completely consistent with his teaching at col. 4 of hypothermic core temperatures that are much higher than the profound hypothermic temperatures taught by Clifton.

The examiner has "taken the position" that, based on the teaching of a heat exchange element temperature of zero degrees Celsius, Ginsburg can be used to induce profound hypothermia. As

stated above, it can't. But it is not up to a patent applicant to produce facts to establish a reverse prima facie case of obviousness. Rather, it is up to the examiner not just to "take a position" but to support it with facts when making the prima facie case ("broad conclusory statements, standing alone, are not evidence", In re Dembiczak, 175 F.3D 994, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999)). Here, absent evidence in support of the examiner's position that the natural warming tendencies of the body would be insufficient to prevent a very small cold object in the venous system from lowering core temperature much below 32°C, the rejection must be reversed. Certainly, Ginsburg itself never makes such an erroneous assumption, so the evidence currently of record in fact rebuts the examiner's position.

Third, it is alleged that Clifton teaches using cooling blankets, and Ginsburg teaches that its catheter is "superior to older simpler methods such as cooling blankets (col. 1, lines 63-64)". A reading of the relied-upon passage shows that the allegation transparently is incorrect. Ginsburg suggests that its catheter, when used for its primary purpose (heating, not cooling), might be superior to ***warming*** blankets and other methods for treating (not inducing) hypothermia. The rejection is thus based on a clearly erroneous finding of fact, and consequently must be reversed under the APA.

8(b) Argument

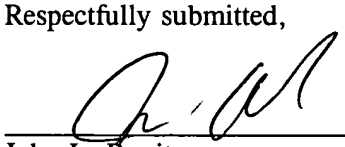
Claim 8 has been rejected under 35 U.S.C. §103 as being unpatentable over Dato in view of Williamson, IV et al. Dato does not teach minimally invasive heart surgery, as recited in Claim 8. Dato teaches using its catheter pursuant to a thorectomy, col. 4, lines 15-30. No suggestion of a minimally invasive approach exists in Dato. The rejection attempts to remedy this shortfall in two

ways, first by making observations about the progression of the last 37 years and second by alleging that Williamson, IV et al. teaches inducing hypothermia for minimally invasive heart surgery.

As much as Appellant would love to discuss the examiner's views on the last 37 years over a pleasant meal, for purposes of this appeal Appellant will confine itself to addressing the references at hand. First, Dato's device is intended for use in a thorectomy, where there is much more room for a surgeon and surgical devices to maneuver than in minimally invasive surgery. There is thus no expectation given by Dato that it could be used in a minimally invasive scenario.

Second, it is simply incorrect that Williamson, IV et al. teaches "providing hypothermia". The only place "hypothermia" is mentioned in Williamson, IV et al. is in col. 2, discussing that one drawback of suturing by hand is that the patient is hypothermic for an inordinate amount of time. This is nothing more than an observation of the well known phenomenon that accidental hypothermia occurs in the Operating Room. It is a problem that Williamson, IV et al. seeks to ameliorate, not to induce, and to do so not by controlling temperature using anything, much less using a catheter, but simply by providing a more rapid procedure. It clearly is not a teaching of inducing hypothermia or of controlling patient temperature, in contrast to the allegation in the rejection.

Respectfully submitted,



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APPENDIX A - CLAIMS

5. A method for treating a human patient, comprising the acts of:

advancing a heat exchange catheter device into the patient;

circulating coolant through the catheter device while preventing infusion of the coolant directly into the patient's bloodstream, the catheter device including at least one heat exchange region; and

performing aneurysm surgery while the patient's temperature is below normal body temperature.

8. A method for treating a human patient, comprising the acts of:

advancing a heat exchange catheter device into the patient;

circulating coolant through the catheter device while preventing infusion of the coolant directly into the patient's bloodstream, the catheter device including at least one heat exchange region; and

performing minimally invasive heart surgery on the patient while the patient's temperature is below normal body temperature.